UTILITY
PATENT APPLICATION
TRANSMITTAL

(only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	JBP-521
First Named Inventor or Application Identifier	Librizzi, et al
Express Mail Label No.	EL190926040US

APPLICATION ELEMENTS

See MPEP Chapter 600 concerning utility patent application contents.

1. ☒ Fee Transmittal Form *(attached hereto in duplicate)*
2. ☒ Specification [Total Pages 22]
(Preferred arrangement set forth below)
 - Descriptive Title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R&D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings *(if filed)*
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☐ Drawing(s)*(35 USC 113)*   [Total Sheets   ]
4. Oath or Declaration
   a. ☐ Newly executed (original or copy)
   b. ☒ Unexecuted original
   c. ☐ Copy from a prior application (37 CFR 1.63(d))
       (for continuation/divisional check boxes 5 and 16)
       i. ☐ Deletion of Inventor(s)
           Signed statement attached deleting
           inventor(s) named in the prior application,
           see 37 CFR 1.63(d)(2) and 1.33(b).
5. ☐   Incorporation by Reference
        (useable if Box 4c is checked)
        The entire disclosure of the prior application, from
        which a copy of the oath or declaration is supplied
        under Box 4c, is considered as being part of the
        disclosure of the accompanying application and is
        hereby incorporated by reference therein.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

6. ☐ Microfiche Computer Program (Appendix)
7. Nucleotide and/or Amino Acid Sequence
    Submission (if applicable, all necessary)
   a.☐Computer Readable Copy
   b.☐Paper Copy (identical to computer copy)
   c.☐Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS
8. ☐ Assignment Papers (cover sheet &
document(s))
9. ☐ 37 CFR 3.73(b) Statement
(when there is an assignee) ☐Power of Attorney
10.☐ English Translation Document *(if applicable)*
11.☐ Information Disclosure Statement
    (IDS)/PTO-1449 ☐Copies of IDS Citations
12.☐ Preliminary Amendment
13.☒ Return Receipt Postcard (MPEP 503)
    (Should be specifically itemized)
14.☐ Certified Copy of Priority Document(s)
    (if foreign priority is claimed)

15.☐ Other:

16. ☐ If a CONTINUING APPLICATION, *check appropriate box and supply the requisite information:*
    Amend the specification by inserting before the first line: -- This is a ☐ Continuation ☐ Divisional
    ☐ Continuation-in-Part (CIP) of prior application No.:   , filed   . --
17.   For this divisional application, please cancel original Claims   of the prior application before calculating the filing
fee.

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SIGNATURE		
DATE	September 29, 2000	

FEE TRANSMITTAL

FEE CALCULATION

CLAIMS AS FILED

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FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE $690.00
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INDEPENDENT CLAIMS	6 - 3 = 3	3	x 78.00	$ 234.00
MULTIPLE DEPENDENT CLAIMS	☐	N/A	$260.00	
			TOTAL FEES	$924.00

METHOD OF PAYMENT

☒ Please charge Deposit Account No. 10-0750/JBP-521/MGM in the amount of $924.00. Three copies of this sheet are enclosed.

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SUBMITTED BY:		Complete (if applicable)
Typed or Printed Name	Michele G. Mangini	Reg. No. 36806
Signature	_(signature)_	Date: September 29, 2000	Deposit Account No. 10-0750/JBP-521/MGM

METHOD FOR CALMING HUMAN BEINGS USING PERSONAL CARE COMPOSITIONS

CROSS-REFERENCE TO RELATED APPLICATION

This Application claims the benefit of United States Application Number 60/157,371 filed on 1 October 1999, which is incorporated by reference in its entirety herein.

FIELD OF THE INVENTION

This invention relates to administering personal care compositions to humans where said compositions contain sensory fragrances.

BACKGROUND OF THE INVENTION

Many currently marketed fragrant cosmetic products claim to have a "calming", "stimulating" or "relaxing" benefit to the user. Typically, these products possess fragrances that are purported to deliver these benefits. To support these claims, several methods have been employed to measure the effects of fragrance on physiological parameters with varying degrees of success and unfortunately, much of the evidence for these purported benefits is the subject of folklore, rather than science.

Cortisol is an adrenocortical hormone which can be found in the blood and the saliva of human beings. Cortisol is produced in the adrenal cortex and is involved in a number of neurological events. Some have found that the level of this hormone rises when an individual is subjected to psychological and physiological stress. Kirschbaum, C. & Hellhammer, D. H., "Salivary Cortisol in Psychoendocrine Research: Recent Developments and Applications"; Psychoendocrinology, Vol. 19 No. 4, 1994, pp. 313-333.

Others have found that when adults are subjected to psychological stress (practicing arithmeetic under stressful conditions) that their level of stress can be monitored by their salivary cortisol. Tanizawa, "A Method for the Determination of the Anti-Stress Effects of Fragrances" JP Patent No.11-19076. The same researchers have shown that if the same individuals were exposed to certain fragrances before the stressful event, their level of salivary cortisol levels would not be as high as when they were psychologically challenged without the fragrance. Id. In this study, the subjects were of the age where they could perform arithmetic calculations. In addition this study showed that not all fragrances were effective at reducing the stress induced release of cortisol. Fragrances with lavender oil or mint oil successfully lowered cortisol levels, while the fragrance with skatole had the opposite effect.

Aside from cortisol levels, there are other indicators that correlate with stress levels in human beings, such as secretory immunoglobulin A (sIgA). See EP 978273 (an increase in sIgA signifies an increase in relaxation) and Stone, et al., "Evidence that Secretory IgA antibody is associated with daily mood," 52(5) J. Personality and Social Psychology 988-93 (1987)("Stone"). sIgA is a secretory immunoglobulin that is found in the saliva of human beings.

It would be desirable to find other fragrance compositions that are capable of reducing stress, and in particular to find such fragrance compositions that are capable of reducing stress in children. More specifically, when children, i.e., those having an age of about 1 day to about 12 years, are subjected to stressful situations, they do not smile, they cry and they do not sleep well. It would be most advantageous for the children if there were a method of reducing these physical symptoms of stress.

SUMMARY OF THE INVENTION

This invention relates to a method of calming mammals including humans, and in particular those having an age between about 1 day to about 12 years, comprising administering to said mammals a personal care composition which comprises an effective amount of a sensory fragrance. Particularly, the invention includes a method of increasing smiling of humans, in particular those having an age of about 1 day to about 12 years, comprising administering to said humans a personal care composition which is comprised of an effective amount of a sensory fragrance. Further, the invention includes a method of reducing crying in humans, in particular those having an age of about 1 day to about 12 years, comprising administering to said humans a personal care composition which comprises an effective amount of a sensory fragrance. Still further, the invention includes a method of improving sleep behaviors in mammals including humans and in particular those having an age of about 1 day to about 12 years, comprising administering to said mammals a personal care composition which comprises an effective amount of a sensory fragrance. Yet still further, the invention includes a method of soothing mammals including humans and in particular those having an age of about 1 day to about 12 years, comprising administering to said mammals a personal care composition which comprises an effective amount of a sensory fragrance.

In addition, the invention includes a personal care composition comprising an effective amount of a sensory fragrance, wherein the sensory fragrance comprises essential oils selected from one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin. Still further, the invention includes a personal care composition comprising an effective amount

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of a sensory fragrance, wherein the sensory fragrance comprises essential oils selected from one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin, and wherein the personal care composition reduces the cortisol levels of a mammal by about 0.1% to about 75% and/or increases the sIgA levels of by about 10% to about 150%.

Another additional aspect of the invention includes a method of increasing the smiling of a human comprising administering to said human a personal care composition comprising an effective amount of a sensory fragrance wherein the sensory fragrance comprises essential oils selected from one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin. Still further, the invention includes a method of calming a mammal comprising administering to said mammal a personal care composition comprising an effective amount of a sensory fragrance where the sensory fragrance comprises essential oils selected from one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin, and wherein said personal care composition reduces the cortisol levels of a mammal being by about 0.1% to about 75% and/or increases sIgA levels of a human being by about 10% to about 150%.

DETAILED DESCRIPTION OF THE INVENTION

This invention relates to a method of calming mammals including humans, and in particular those having an age of from about 1 day to about 12 years, comprising administering to the mammals a personal care composition which comprises an effective amount of a sensory fragrance. The preferred age of a human who is calmed by this invention is 1 week to 5 years, more preferably 1 week to 3 years, most preferably between about 1 week to about 2 years.

As used herein "calming" refers to the psychological aspects of well being, namely the feeling of good will, relaxation and/or the absence of malice and aggravation.

As used herein, "mammals" include any of a class of warm–blooded higher vertebrates that nourish their young with milk secreted by mammary glands and have skin usually more or less covered with hair, and non-exclusively includes humans, dogs and cats.

The term "administering" refers to the (i) inhalation of a topically applied personal care composition; (ii) inhalation of the vapors which are released when a personal care composition is dissolved or dispersed in a liquid vehicle such as water, or (iii) inhalation of

vapors which are released when a personal care composition is dispersed, sprayed, melted or burned.

The term "effective amount" refers to the percentage by weight of the sensory fragrance, with respect to the overall weight of the personal care composition, which is needed to create the desired response in a mammal, and in particular a human being having an age of about 1 week to about 12 years. Examples of desired responses include improved sleep, increased calmness, increased relaxation, and increased smiling. Preferably the effective amount is less than about 30%, by weight of the fragrance, more preferably between about 0.1% and about 10%, most preferably between about 0.2% and about 2%.

The "sensory fragrance" is comprised of volatile oils that may be extracted from a natural or synthetic source. The sensory fragrance may also further include other odoriferous components that may be used for purposes of improving the appeal to the consumer of the personal care compositions of the invention. The preferred sensory fragrance comprises, based upon the total weight of the sensory fragrance, from about 0.01% to about 30%, e.g., from about 0.1% to about 10%, and from about 0.1% to about 8 % of the essential oils, and from about 70% to about 99.99%, e.g. from about 90% to about 99.9%, and from about 92% to about 99.9% of the other odoriferous components.

The preferred sensory fragrance is comprised of essential oils selected from one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin.

Typically, the essential oil portion of the sensory fragrance is comprised of, based upon the total weight of the total fragrance, from about 0.05 % to about 5% chamomile, about 0.01% to about 5% rose, about 0.5% to about 30% orange, about 0.01% to about 5% tuberose, about 0.01% to about 25% sandalwood, about 0.01% to about 30% lavender, about 0.1% to about 30% cedarwood, about 0.01% to about 30% bergamot, and about 0.1% to about 15% benzoin resin. Alternatively, the essential oil portion of the sensory fragrance is comprised of, based upon the total weight of the total fragrance, from about 0.05% to about 3% chamomile, between about 0.01% to about 3% rose, between about 0.5% to about 15% orange, between about 0.01% to about 3% tuberose, between about 0.01% to about 15% sandalwood, between about 0.01% to about 15% lavender, between about 0.1% to about 30% cedarwood, between about 0.01% to about 15% bergamot, and between about 0.1% to about 10% benzoin resin. In another embodiment, the essential oil portion of the sensory fragrance is comprised of, based upon the total weight of the fragrance, from about 0.05% to about 2% chamomile, from about 0.01% to about 1.5% rose, from about 0.5% to about 10% orange, from about 0.01% to about 1.5% tuberose, from about 0.01% to

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about 10% sandalwood, from about 0.01% to about 10% lavender, from about 0.1% to about 30% cedarwood, from about 0.01% to about 10% bergamot, and from about 0.1% to about 5% benzoin resin.

The other odoriferous components of the sensory fragrance include but are not limited to benzenoid materials, alcohol materials, ester materials, aldehyde materials, ketone materials, and mixtures thereof. The benzenoid materials are selected from benzyl benzoate, benzyl carbinol, benzyl salicylate, benzyl cinnamate, diethyl phthalate, phenoxy ethanol, hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-γ-2-benzopyran, 7-acetyl-1,1,3,4,4,6-hexamethyltetralin, 3-(3,4-methylene dioxyphenol)-2-methyl propanol, methyl-iso-eugenol, eugenol, and mixtures thereof. The alcohol materials are selected from citronellol, alcohol C-8, alcohol C-10; alcohol C-11, alcohol C12, dipropylene glycol, linalool, geraniol, benzyl alcohol, 2-ethyl-4-(2,2,3-trimethyl-3-cyclopentene-1-yl)-2-buten-l-ol, dihydromyrcenol, and mixtures thereof. The aldehyde materials are selected from 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene 1-carboxoaldehyde, p-t-butyl-α-methyldihydrocinnamic aldehyde, aldehyde C-10, aldehyde C-11, aldehyde C-12, laurinal, heliotropine, anisic aldehyde, benzyl aldehyde, and mixtures thereof. The esters materials are selected from benzyl acetate, dimethyl benzyl carbinyl acetate, ethylene brassylate, cyclopentadecanolide, linalyl acetate, benzyl proprionate, citronellyl acetate, hexyl butyrate, neryl acetate, prenyl acetate, hexyl cinnamate, oxacyclohexadecen-2-one, and mixtures thereof. The ketones materials are selected from methyl ionone, ambretone, methyl dihydro jasmonate, muscone, allyl ionone, and mixtures thereof.

The sensory fragrance may be produced by blending the selected essential oils and odoriferous components under ambient conditions until the final mixture is homogenous using equipment and methodology commonly known in the art of fragrance compounding. It is preferable to store the final sensory fragrance mixture under ambient conditions for a few hours after mixing before using it as a component of a personal care composition. The personal care compositions of the present invention may then be produced by blending the desired components with the sensory fragrance using equipment and methodology commonly known in the art of personal care product manufacture. In order to improve the solubilization of the sensory fragrance in aqueous personal care compositions, the sensory fragrance may be pre-blended with one or more of the nonionic surfactants.

"Personal care compositions" refers to personal cosmetic, toiletry, and healthcare products such as wipes, washes, baths, shampoos, gels, soaps, sticks, balms, sachets, pillows, mousses, sprays, lotions, creams, cleansing compositions, powders, oils, bath oils and other bath compositions which may be added to a bath. Personal care compositions may also include, but are not limited to, aerosols, candles, and substances that may be

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used with vaporizers. The aforementioned wipes, washes, baths, shampoos, gels, soaps, sticks, balms, sachets, pillows, mousses, sprays, lotions, creams, cleansing compositions, oils, bath oils, aerosols, candles and substances which may be used with vaporizers are commercially known to those who have a knowledge of preparing personal care compositions.

The preferred personal care compositions of the invention are lotions, powders, bath oils and other bath additives wherein the use of the personal care compositions of the present invention is capable of reducing the cortisol levels of a mammal by about 0.1% to about 75% after the personal care composition is administered to said mammal and/or those capable of increasing the sIgA levels of a mammal by about 10% to about 150%, preferably from about 20% to about 70%. The cortisol levels of a mammal are typically reduced within about 20 minutes to about 30 minutes after administration of the personal care composition of the present invention thereto. The sIgA levels of a mammal are typically increased within about 1 minute to about 10 minutes after administration of the personal care composition of the present invention thereto. The sIgA levels may be measured in accordance with sIgA methods known in the art such as, for example, those disclosed in Stone, which is incorporated by reference herein.

In order to achieve the desired response in a mammal, the personal care composition may be used in a dosing amount that is in accordance with the prescribed directions of the personal care composition.

Particularly, the invention includes a method of increasing smiling of a human having an age of about 1 day to about 12 years comprising administering to said human a personal care composition which comprises an effective amount of the sensory fragrance. The preferred age of a human whose smiling is increased by this invention is about 1 week to about 5 years, more preferably about 1 week to about 3 years, most preferably between about 1 week to about 2 years.

Further, the invention includes a method of reducing crying in a human having an age of about 1 day to about 12 years comprising administering to said human a personal care composition which comprises an effective amount of the sensory fragrance. The preferred age of a human whose crying is reduced by this invention is about 1 week to about 5 years, more preferably about 1 week to about 3 years, most preferably between about 1 week to about 2 years.

Still further, the invention includes a method of improving sleep behaviors in a mammal including a human and in particular a human having an age of about 1 day to about 12 years comprising administering to said mammal a personal care composition · which comprises an effective amount of the sensory fragrance. The preferred age of a

human whose sleep behaviors are improved by this invention is about 1 week to about 5 years, more preferably about 1 week to about 3 years, most preferably between about 1 week to about 2 years.

Yet still further, the invention includes a method of soothing a mammal, and in particular a human having an age of about 1 day to about 12 years, comprising administering to said mammal a personal care composition which comprises an effective amount of the sensory fragrance. The preferred age of a human who is soothed by this invention is about 1 week to about 5 years, more preferably about 1 week to about 3 years, most preferably between about 1 week to about 2 years. The term "soothing" as used herein, refers to bringing peace, composure, relief, or quietude to a human having an age of about 1 day to about 12 years. It is generally apparent that when children in particular are soothed, they cry less, and sleep better.

In addition, the invention includes a personal care composition comprising an effective amount of the sensory fragrance, where the sensory fragrance comprises essential oils selected from one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin. The preferred sensory fragrance of the invention contains the essential oils chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin.

Still further, the invention includes a personal care composition comprising an effective amount of the sensory fragrance, where the sensory fragrance comprises essential oils selected from one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin, where said personal care composition reduces the cortisol levels of a mammal by about 0.1% to about 75%, e.g. from about 20% to about 40%, from about 10% to about 50%, or from about 15% to about 35% and/or increases the level of sIgA by about 10% to about 150%, e.g. from about 20% to about 70% or from about 40% to about 55%. Preferably, the reduction of cortisol level and the increase in IgA level are measured in the saliva of a mammal.

Another additional aspect of the invention includes a method of increasing the smiling of a human comprising administering to said human a personal care composition comprising an effective amount of the sensory fragrance wherein the sensory fragrance comprises essential oils selected from one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, benzoin resin.

Still further, the invention includes a method of calming a mammal comprising administering to said human a personal care composition comprising an effective amount of the sensory fragrance wherein the sensory fragrance comprises essential oils selected from

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one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin, where said personal care composition reduces the cortisol levels of a mammal by about 0.1% to about 75% and/or increases the sIgA levels of a mammal by about 10% to about 150%.

One method of soothing a mammal, in particular a human having an age of 1 week to about 1 year, is via the use of the personal care composition of the present invention that is comprised of, based upon the total weight of the personal care composition, from about 98.5% mineral oil and about 1.5% of the sensory fragrance, which is preferably comprised of the following essential oils in amounts based upon the total weight of the fragrance: about 1% chamomile, about 0.75 % rose, about 5% orange, about 0.5 % tuberose, about 7.5% sandalwood, about 8 % lavender, about 4.8% cedarwood, about 9.6% bergamot, and about 0.7.% benzoin resin. The personal care composition may be massaged or rubbed onto the skin of a human being at any time, but typically the personal care composition is administered before bedtime.

In order to illustrate the invention the following examples are included. These examples do not limit the invention. They are meant only to suggest a method of practicing the invention. Those knowledgeable in the calming of human beings as well as other specialties may find other methods of practicing the invention. Those methods are deemed to be within the scope of this invention.

EXAMPLES

Example 1.:Preparation of Personal Care Composition A with Sensory Fragrance
Takasago Fragrance # RK-2086/1, (containing 50% benzenoid material, 25% alcohol material, 12% ester material, 7% aldehyde material, 5% essential oils, and 1% ketone material) was mixed with a cleansing surfactant composition. This cleaning surfactant composition contains sodium lauroamphodiacetate, sodium laureth-13 carboxylate, sodium trideceth sulfate, polysorbate-20, PEG-150 distearate, POE 80 sorbitan monolaurate, cocamidopropyl betaine, tetrasodium EDTA, quaternium 15, citric acid, USP, sodium chloride, and water where the percentages of components in the personal care composition are listed in Table A.

Table A

INCI Name	% Active	% (wt/wt)	% Active (wt/wt)
Disodium Lauroamphodiacetate	30	2.700	0.810
Sodium Laureth-13 Carboxylate	70	1.350	0.945
Sodium Trideceth Sulfate	30	9.000	2.700
Polysorbate-20	100	0.500	0.500
PEG-150 Distearate	100	0.700	0.700
POE 80 Sorbitan Monolaurate	72	6.000	4.320
Fragrance	100	1.000	1.000
Cocamidopropyl Betaine	30	12.50	3.750
Tetrasodium EDTA	38	0.200	0.076
Quaternium 15	100	0.049	0.049
Citric Acid, USP	100	0.200	0.20
Sodium Chloride	100	2.000	2.00
Water	0	63.80	0

Example 2: Preparation of Personal Care Composition B without Sensory Fragrance

      Personal Care Composition B contains a cleaning surfactant system which contains: Disodium Lauroamphodiacetate, Sodium Laureth-13 Carboxylate, Sodium Trideceth Sulfate, Polysorbate-20, PEG-150 Distearate, POE 80 Sorbitan Monolaurate, Fragrance, Cocamidopropyl Betaine, Tetrasodium EDTA, Quaternium 15, Citric Acid, USP, Sodium Chloride, and Water in the same relative ratios as the 99% portion of Personal Care Composition A.

Example 3: Bathing Infants with Personal Compositions
 A and B and Determining Their Salivary Cortisol Levels

      Saliva samples were taken from groups of children having an age of 1 week to 4 months and their care givers. Said saliva was tested to determine the baseline salivary cortisol levels. Subsequently, the same infants were given a bath by their caregivers using Personal Care Composition B. Saliva samples were collected 20 minutes after the bathing procedure and salivary cortisol levels were measured. This group is the control group, Group 2.

      Saliva samples were taken from another group of children of a similar age. Subsequently, these children were bathed with Personal Care Composition A. Saliva samples were collected 20 minutes after the bathing procedure and salivary cortisol levels were measured. This group is the testing group, Group 1.

      The changes in cortisol levels of the infants and caregivers in Group 1 and Group 2 are shown in Table I.

TABLE I

Salivary Cortisol Level Change (Post bath– Initial)

Subject	Group 1 (% CCL***)	Group 2 (% CCL)
Mother*	-8.2 ± 7.0[2]	-0.4 ± 4.3
Child**	- 15.4 ± 19.7[1]	+19.6 ± 29.3

1. Group 1 demonstrates a statistically significant change from initial at a 94% confidence interval.
2. Group 1 demonstrates a statistically significant change from initial at a 99% confidence interval.
* Group 1 demonstrates statistically significant difference from Group 2 at 99% confidence interval
** Group 1 demonstrates statistically significant difference from Group 2 at 98% confidence interval
*** "CCL" means the change in cortisol level.

Example 4: Observed Behaviors of Infants and Caregivers

Another group of 10 children and their caregivers followed the bathing procedures of Example 3. The bathing procedures were monitored on videotape. Children and their caregivers were observed and the results were tabulated in Table II.

TABLE II

Observed behavior during bath

Behavior	Group 1 (% Occurrence)	Group 2 (% Occurrence)
Mother Smiling	37.0 ± 25.1	16.4 ± 13.9
Mother Touching Baby[2]	90.2 ± 11.5	65.2 ± 20.7
Child Looking at Mother[1]	87.4 ± 5.9	65.0 ± 26.8

1. Group 1 demonstrates statistically significant difference from Group2 at 90% confidence interval.
2. Group 1 demonstrates statistically significant difference from Group2 at 95% confidence interval.
3. Group 1 demonstrates statistically significant difference from Group2 at 99% confidence interval.

Example 5

Sleep Behaviors after Bathing

Another group of 10 children and their caregivers followed the bathing procedure of example 3. After the bath the children were placed in a quiet place and were allowed to go to sleep. During this period, sleep measurements, including sleep delay behaviors, the latency of sleep (time until onset), sleep stages (grimacing and movements) and activity level were observed and are tabulated below.

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TABLE II

Observed behavior after bath

Behavior	Group 1 (% Occurrence)	Group 2 (% Occurrence)
Infant in Deep Sleep[3]*	42.2 ± 15.8	9.4 ± 17.3
Infant Crying	28.4 ± 30.8	52.1 ± 38.7

1. Group 1 demonstrates statistically significant difference from Group2 at 90% confidence interval.
2. Group 1 demonstrates statistically significant difference from Group2 at 95% confidence interval.
3. Group 1 demonstrates statistically significant difference from Group 2 at 99% confidence interval.
* By "deep sleep" it is meant that the subject infant rested in a relaxed manner with minimal grimacing and movements.

Upon review of the records for the studies performed in accordance with Examples 1 through 5, it was unclear whether or not these studies were performed in accordance with the prescribed protocol. In view of this uncertainty, similar additional studies were performed as set forth below in Examples 6 - 8.

Example 6: Fragranced Bath and saliva collection

    A total of eleven male and female children having an age of about 9 to 11 years participated in a bathing study in which their respective saliva samples were collected both before and after bathing for the purpose of measuring salivary cortisol concentrations and salivary sIgA concentrations.

    Immediately prior to bathing, about 1 ml of an initial saliva sample was collected from each respective child via having each child drool or spit into an independent vial. These samples were then frozen until subsequent cortisol concentration and sIgA analyses.

    Each child was then asked to bathe independently for a period of 10 minutes in a bath of water having a temperature of 33 °C to 35°C. The bath had been filled to a level approximately mid way on each child's torso when seated in the bathtub. Sixty grams of the fragranced bath of Example 1 were then added to the bath.

    Thirty minutes after each child had finished bathing, about 1 ml of a post-bathing saliva sample was collected from each child via having each child drool or spit into a second independent vial. This second sample was also frozen for subsequent cortisol and IgA concentration analyses.

Example 7– Bathing with Unfragranced Bath and collection

    A total of 10 male and female children having an age of about 9 to 11 years participated in a second bathing study in which their saliva samples were collected both

before and after bathing for the purpose of measuring salivary cortisol concentrations and salivary sIgA concentrations. Each child repeated the procedure set forth in Example 6, with the exception that an unfragranced bath of Example 2 was added to the bath in place of the fragranced bath.

Example 8: Salivary Cortisol Testing

Saliva samples obtained from the studies of Example 6 and Example 7 were tested for cortisol concentrations by Salimetrics, LLC using a "SALIMETRICS HS-CORTISOL HIGH SENSITIVITY SALIVARY CORTISOL ENZYME IMMUNOASSAY KIT" available from Salimetrics, LLC in its catalog as "Catalog No. 0101 96-Well Kit" in accordance with the instructions contained therein.

The results of the cortisol analyses for examples 7 and 8 are reported in Tables III and IV.

Table III

Example 6	Cortisol (μg/dl)		
Panelist #	Before	After	Change
A	0.472	0.243	-0.229
B	0.084	0.113	0.029
C	0.538	0.187	-0.351
D	0.149	0.112	-0.037
E	0.16	0.128	-0.032
F	0.134	0.13	-0.004
G	0.29	0.176	-0.114
H	0.174	0.131	-0.043
I	0.145	0.076	-0.069
J	0.274	0.214	-0.06
K	0.208	0.158	-0.05

Table IV

Example 8	Cortisol (μg/dl)		
Panelist #	Before	After	Change
A	0.703	0.251	-0.452
B	0.191	0.116	-0.075
C	0.128	0.12	-0.008
D	0.177	0.073	-0.104
E	0.207	0.098	-0.109
F	0.074	0.049	-0.025
G	0.202	0.097	-0.105
H	0.156	0.081	-0.075
I	0.125	0.091	-0.034
J	0.195	0.119	-0.076
K	0.147	0.087	-0.06

This Example showed that both bath products were effective at reducing the cortisol levels of the children.

Example 9: Salivary sIgA analysis

Saliva samples obtained from the studies of Example 6 and Example 7 were tested for salivary sIgA concentrations by Salimetrics, LLC in accordance with the protocol below and the materials and protocol provided in the kit of Example 8.

After thawing the saliva samples from a temperature of − 80 °C, the samples were vortexed, and centrifuged at 1500 x g for 15 minutes. A 1:2000 dilution of the saliva was made using the buffer solution. 100 μl of calibrators and diluted saliva samples were then added to a microtiter plate coated with polyclonal rabbit antibodies to sIgA and incubated for 1 hour, with constant shaking at room temperature. After incubation, the plate was aspirated and washed 5x with 250 μl wash buffer to remove all unbound substances. 100 μl of peroxidase-labelled anti-sIgA antibody was then added to each well on the microtiter plate. After incubating the plate for 30 minutes with constant shaking at room temperature, the contents of the plate were decanted and washed 5x with the 250 μl wash buffer to remove all unbound substances. 100 μl of tetramethylbenzidine (TMB) substrate solution was added and incubated for 15-20 minutes at room temperature with no mixing. This enzyme acted on the substrate and caused a blue color to appear in proportion to the amount of peroxidase present. 50 μl of the stop solution was then added to the wells and the OD (optical density) was read on the plate reader at 450 nm. A yellow color was formed after stop solution was added. The amount of color detected was directly proportional to the amount of sIgA present.

Using values obtained from the calibrators, a dose response curve of the optical density verses concentration was then plotted. The level of secretory IgA in each sample was then determined from this curve.

The results of the sIgA analyses for examples 6 and 7 were are reported in Tables V and VI below.

Table V

Example 6	sIgA (μg/ml)		
Panelist #	Before	After	Change
A	275.67	145.93	-129.74
B	None detected	223.31	Not applicable
C	499.59	261.58	-238.01
D	518.77	451.78	-66.99
E	408.05	124.21	-283.84
F	954.27	522.98	-431.29
G	221.64	99.33	-122.31
H	119.05	119.08	0.03
I	106.66	219.09	112.43
J	201.74	279.83	78.09
K	167.8	206.62	38.82

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Table VI

Example 7	slgA (µg/ml)		
Panelist #	Before	After	Change
A	None detected	139.32	Not applicable
B	386.33	748.7	362.37
C	92.62	120.04	27.42
D	746.25	267.14	-479.11
E	310.79	461.91	151.12
F	254.18	171.65	-82.53
G	407.92	369.79	-38.13
H	221.04	211.2	-9.84
I	687.59	194.51	-493.08
J	627.52	None detected	Not applicable
K	260.37	196.3	-64.07

This Example did not reveal a consistent trend in the change of slgA concentration.

While not wishing to be bound to the theory, it was considered that the 30 minute time point for saliva collection for slgA might have been too long from the period of exposure. Therefore, it was decided to repeat the slgA analyses, but with a shorter time period between exposure and slgA sampling. The results of these studies are set forth in Examples 10 to 13 below.

Example 10 - Effect of Sensory Fragrance on slgA

Approximately 1ml of saliva was collected in vials from a total of 8 male and female adults by having each adult drool or spit into an independent vial. The samples were frozen until later analyzed for slgA concentration.

Each adult was then asked to frequently smell an open container containing the sensory fragrance used in the composition of Example 1 over a 5 minute period. Ten minutes after the completion of smelling the container, a second saliva sample was collected from each adult in an independent vial and stored as set forth above.

Five minutes following collection of the second saliva sample, a third saliva sample was collected from each adult and stored as set forth above.

Example 11 - Effect of Unfragranced composition on slgA

The procedure of Example 10 was repeated with a total of 8 additional male and female adults, but the sensory fragrance was replaced with the unfragranced bath composition of Example 2.

Example 12 – Effect of a bath on sIgA

Approximately 1ml of saliva was collected in vials from a total of eight male and female adults by having each adult drool or spit into an independent vial. The samples were frozen as set forth above in Example 6 until later analyzed for sIgA concentration.

Each volunteer was then asked to bathe in a tub of warm water for a period of 15 minutes.

Ten minutes after having finished bathing, a second saliva sample was collected and stored as set forth above.

Example 13 – Effect of a bath with Fragranced Bath on sIgA

Approximately 1ml of saliva was collected in vials from a total of eight male and female adult volunteers by having each adult drool or spit into an independent vial. The samples were then frozen as set forth above in Example 6 until later analyzed for sIgA concentration.

Each volunteer was then asked to bathe in a tub of warm water containing 30 g of the bath composition of Example 1 for a period of 15 minutes.

Ten minutes after having finished bathing, a second saliva sample was collected and stored in the same way as the first saliva sample.

The samples were then analyzed for sIgA as described above in Example 9. The results of the sIgA analyses for examples 10, 11, 12, and 13, respectively, are reported in Tables VII, VIII, IX, and X, respectively, below.

Table VII- Sensory Fragrance

Example 10	SIgA (µg/ml)		
Panelist #	Before	After	Change
1	214.35	155.25	-59.1
2	79.11	178.32	99.21
3	81.05	168.06	87.01
4	129.64	271.23	141.59
5	167.75	167.01	-0.74
6	194.94	178.18	-16.76
7	85.03	175.74	90.71
8	174.97	110.18	-64.79

Table VIII – No sensory fragrance

Example 11	SIgA (μg/ml)		
Panelist #	Before	After	Change
1	159.9	153.82	-6.08
2	261.33	200.93	-60.4
3	150.58	131.4	-19.18
4	469.66	208.61	-261.05
5	212.73	350.69	137.96
6	107.1	108.94	1.84
7	172.57	147.3	-25.27
8	66.29	107.93	41.64

The data in Tables VII and VIII demonstrate that the sIgA concentrations of the panelists significantly increased by an average of about 47% after each adult inhaled the sensory fragrances of the present invention. The average increase in sIgA for panelists who inhaled the unfragranced material was only about 2%. This data was found to be statistically significant at a confidence level of 85%. This Example showed that the present invention is effective in increasing sIgA concentrations, which also correlates with a reduction of stress.

Table IX - Bath

Example 12	sIgA (μg/ml)		
Panelist #	Before	After	Change
1	201.97	113.15	-88.82
2	237.69	218.85	-18.84
3	163.75	205.96	42.21
4	488.34	115.3	-373.04
5	165.52	94.93	-70.59
6	45.44	52.63	7.19
7	116.67	86.2	-30.47
8	113.43	166.48	53.05

Table X – Fragranced Bath

Example 13	sIgA (μg/ml)		
Panelist #	Before	After	Change
1	89.48	79.42	-10.06
2	142.61	164.79	22.18
3	NA	NA	NA
4	415.78	191.19	-224.59
5	219.77	254.56	34.79
6	60.8	108.38	47.58
7	70.45	56.2	-14.25
8	126.78	158.21	31.43

The data in Tables IX and X showed that the sIgA changes for the panelists who bathed in water containing the sensory fragrances of the present invention were comparable to those recorded by the panelists who bathed in the water alone.

Each of the panelists who participated in the studies of Examples 10 to 13 were also given a questionnaire regarding how they each felt after the completion of the study. More specifically, the questionnaire addressed whether or not the panelists felt good, soothed, relaxed, more at ease, less stressed, safe, comforted, and/or calm after inhaling the compositions (either alone or in a bath) of the study. The results of the questionnaire for panelists who only inhaled compositions (e.g. those of Examples 10 and 11) are shown in Table XI. The results of the questionnaire for panelists who inhaled compositions while bathing therein (e.g. those of Examples 12 and 13) are shown in Table XII.

Table XI

Sniff Test	Percent of Panelists who agreed	
Feeling	Unfragranced	Fragranced
Soothed	38	75
Relaxed	50	88
More At Ease	38	88
Feel Good	75	75
Less Stressed	38	75
Safe	25	25
Comforted	25	63
Calm	38	88

Table XII

Bath Test	Percent of Panelists who agreed	
Feeling	Unfragranced	Fragranced
Soothed	57	88
Relaxed	86	100
More At Ease	100	75
Feel Good	86	100
Less Stressed	57	100
Safe	29	38
Comforted	43	75
Calm	71	75

This Example showed that the panelists who inhaled the sensory fragrances (either with or without a bath) felt better and had a more positive experience than those panelists

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who did not inhale the sensory fragrance. Most significantly, as shown in Table XII, all of the panelists reported to have felt relaxed, good, and less stressed after inhaling the sensory composition in a bath.

What is claimed is:

1.   A method of calming a mammal comprising administering to said mammal a
personal care composition which comprises an effective amount of a sensory
fragrance, wherein the personal care composition is capable of reducing the cortisol
level of the mammal by about 0.1 to about 75% and/or increasing the sIgA level of
the mammal by about 10% to about 150%.

2.   The method of claim 1 wherein the sensory fragrance is comprised of one or more
members of the group consisting of chamomile, rose, orange, tuberose,
sandalwood, lavender, cedarwood, bergamot, and benzoin resin.

3.   A method of increasing smiling of a human comprising administering to said human
a personal care composition that is comprised of an effective amount of a sensory
fragrance.

4.   The method of claim 3 wherein the sensory fragrance is comprised of one or more
members of the group consisting of chamomile, rose, orange, tuberose,
sandalwood, lavender, cedarwood, bergamot, and benzoin resin.

5.   A method of reducing crying in a human comprising administering to said human a
personal care composition which comprises an effective amount of a sensory
fragrance.

6.   The method of claim 5 wherein the human has an age of about 1 day to about 12
years.

7.   The method of claim 5 wherein the sensory fragrance is comprised of one or more
members of the group consisting of chamomile, rose, orange, tuberose,
sandalwood, lavender, cedarwood, bergamot, and benzoin resin.

8.   A method of improving sleep behaviors in a mammal comprising administering to
said mammal a personal care composition which comprises an effective amount of
a sensory fragrance.

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9.   The method of claim 8 wherein the sensory fragrance is comprised of one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin.

10.   A method of soothing a mammal comprising administering to said mammal a personal care composition which comprises an effective amount of a sensory fragrance, wherein the personal care composition is capable of reducing the cortisol level of the mammal by about 0.1 to about 75% and/or increasing the sIgA level of the mammal by about 10% to about 150%.

11.   The method of claim 10 wherein the sensory fragrance is comprised of one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin.

12.   A personal care composition comprising an effective amount of a sensory fragrance, where said fragrance comprises one or more members of the group consisting of chamomile, rose, orange, tuberose, sandalwood, lavender, cedarwood, bergamot, and benzoin resin.

13.   The personal care composition of claim 12, wherein the personal care composition is capable of reducing the cortisol level in a mammal by about 0.1 to about 75% and/or increasing the sIgA level in the human by about 10% to about 150%.

14.   The personal care composition of claim 12, wherein the sensory fragrance is comprised of, based upon the total weight of the sensory fragrance, from about 3% to about 7% of essential oils and from about 93% to about 97% of an odoriferous portion containing benzenoid materials, alcohol materials, ester materials, aldehyde materials, ketone materials and mixtures thereof.

15.   The personal care composition of claim 14 where
      the benzenoid materials are selected from benzyl benzoate, benzyl carbinol, benzyl salicylate, benzyl cinnamate, diethyl phthalate, phenoxy ethanol, hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-γ-2-benzopyran, 7-acetyl-1,1,3,4,4,6-hexamethyltetralin, 3-(3,4-methylene dioxyphenol)-2-methyl propanol, methyl-iso-eugenol, eugenol, and mixtures thereof;
      the alcohol materials are selected from citronellol, alcohol C-8, alcohol C-10;

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alcohol C-11, alcohol C12, dipropylene glycol, linalool, geraniol, benzyl
alcohol, 2-ethyl-4-(2,2,3-trimethyl-3-cyclopentene-1-yl)-2-buten-l-ol,
dihydromyrcenol, and mixtures thereof;

the aldehyde materials are selected from 4-(4-hydroxy-4-methylpentyl)-3-
cyclohexene 1-carboxoaldehyde, p-t-butyl-α-methyldihydrocinnamic
aldehyde, aldehyde C-10, aldehyde C-11, aldehyde C-12, laurinal,
heliotropine, anisic aldehyde, benzyl aldehyde, and mixtures thereof;

the ester materials are selected from benzyl acetate, dimethyl benzyl carbinyl
acetate, ethylene brassylate, cyclopentadecanolide, linalyl acetate, benzyl
proprionate, citronellyl acetate, hexyl butyrate, neryl acetate, prenyl acetate,
hexyl cinnamate, oxacyclohexadecen-2-one, and mixtures thereof; and

the ketone materials are selected from methyl ionone, ambretone, methyl
dihydro jasmonate, muscone, allyl ionone; and mixtures thereof.

ABSTRACT

This invention relates to a method of calming mammals comprising administering to said humans a personal care composition which comprises an effective amount of a sensory fragrance that is effective in reducing cortisol levels and/or increasing sIgA levels.

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DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled Method For Calming Human Beings Using Personal Care Compositions, the specification of which

> (check one) ☒ is attached hereto.
>
> ☐ was filed on _____ as
>
> Application Serial No. _____
>
> and was amended on _____.
> (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119	
			☐ YES	☐ NO
			☐ YES	☐ NO
			☐ YES	☐ NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

60/157,371   October 1, 1999
(Application Number)   (Filing Date)

(Application Number)   (Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.   Filing Date   Status

Application Serial No.   Filing Date   Status

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Steven P. Berman (Reg. #24,772), Andrea L. Colby (Reg. #30,194), Paul A. Coletti (Reg. #32,019), Matthew S. Goodwin (Reg. #32,839), Bernard F. Plantz (Reg. #32,091), Joseph F. Shirtz (Reg. #31,880), Michael Stark (Reg. #32,495), Mark R. Warfield

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